UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,595	02/11/2002	Judith A. Kelleher	005699-514	5929

7590 09/03/2003

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	12

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/074,595	Kelleher et al.
Examiner	**Art Unit**
Phyllis G. Spivack	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 16, 2003*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *45-48, 50-52, and 54-61* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *45, 50, and 54* is/are allowed.

6) ☒ Claim(s) *46-48, 51, 52, and 55-61* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants' Amendment/Reply filed June 16, 2003, Paper No. 8, is acknowledged. Claims 45-48, 50-52 and 54-61 remain under consideration.

An Information Disclosure Statement filed June 16, 2003, Paper No. 9, is further acknowledged and has been reviewed to the extent each reference was located in the parent application.

A Terminal Disclaimer filed June 16, 2003, Paper No. 10, is further acknowledged. Accordingly, the rejection of record of claims 45-48, 50-52 and 54-61 under the judicially created doctrine of obviousness-type double patenting is withdrawn.

In the last Office Action claims 46-48, 51, 52 and 55-61 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to practice the invention.

Applicants argue all of the claims have been amended to recite "ameliorating a cause of a disease" rather than "preventing the disease" and urge the Examples in the application depict a number of settings in which a cause of a disease is ameliorated.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record is repeated for the reasons of record.

The rejected claims are directed to the treatment of specific neurodegenerative, autoimmune and inflammatory diseases. The specification provides support for the ability of certain α-aryl-N-alkylnitrones to trap free radicals, to reduce neuronal injury, to reduce Aβ

peptide/ibotenate-induced learning deficit, to reduce cognitive deficits, to inhibit the association of ThT with synthetic Aβ (l-42) and to reduce the CNS inflammatory deficit in acute EAE animals.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the methods of treating the disease states of claims 46-48, 51, 52 and 55-61 without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to amelioration of diseases for which treatment at the present time is often therapeutically unsuccessful.

The relative skill of those in the art is generally that of a Ph.D or M.D.

Each particular disease has its own specific characteristics and etiology. In most aspects the diseases are unrelated.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad in the sense that neurodegenerative, autoimmune and inflammatory processes as they manifest themselves in various disease states are often distinct to the organ system to which they relate.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to trapping free radicals, reducing neuronal injury, reducing Aβ peptide/ibotenate-induced learning deficit, reducing cognitive deficits, inhibiting the association of ThT with synthetic Aβ (l-42) and reducing the CNS inflammatory deficit in acute EAE animals

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular α-aryl-N-alkylnitrone would be preferred for treatment of a specific disease of neurodegenerative, autoimmune or inflammatory origin. The skilled artisan would expect the action of a particular compound in the treatment of a particular disease state to be very specific and highly unpredictable absent a clear

understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding nor any criteria for extrapolating. Absent reasonable *a priori* expectations of success for using a particular chemotherapeutic agent to treat a particular disease, one skilled in the art would have to test extensively many compounds to discover which particular disease responds to that particular compound. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C FR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C FR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

September 1, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER